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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,076

07/24/2003

Andrea Venturelli

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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

02/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/626,076	VENTURELLI, ANDREA	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the step of inserting the guide tube into the distal tube so that the guide tube proximal end exits and extends from the distal tube flared proximal end.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure fails to describe the step of inserting the guide tube into the distal tube being carried out before the step of inserting the two expanders. There is no specific disclosure or support for the step of inserting the guide tube into the distal tube being performed before the step of inserting the expanders. There is disclosure of the step of inserting the expanders before the step of

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fixing the various ends of the tubes by means of a heat-sealing operation but this does not provide disclosure for the step of inserting the guide tube into the distal tube being carried out before the step of inserting the two expanders. The disclosure also fails to describe the step of trimming the guide tube proximal end as there is no mention of cutting or trimming the guide tube proximal end. Furthermore, there is no disclosure of the step of trimming the guide tube proximal end being carried out after the step of extracting the two expanders.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 23, it is unclear if two expanders are being inserted into each of the distal end of the main tube and the proximal end of the guide tube or if one expander is being inserted into each of the main tube and the guide tube. Also, the use of "said tubes" in line 8 of claim 23 is unclear as to whether this refers to all three of the tubes (the distal tube, the guide tube, and the main tube) or the main tube and the guide tube.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (U.S. Patent No. 5,156,594) in view of Zarbatany et al (U.S. Patent No. 6,030,405). In Figure 2, Keith shows or provides a distal tube (82) with a flared proximal end (100), a guide tube (80) with a proximal end (32), and a main tube (22) with a distal end (68). As seen in Figure 2, at least part of the distal end (68) of the main tube is deflected and inclined towards the axis of the main tube. The deflected and inclined distal end (68) of the main tube (22) is inserted into the distal tube flared proximal end (100) so that the proximal end (32) of the guide tube (80) is put on the outside of the deflected and inclined distal end (72). Keith teaches joining or fixing the distal end (68) of the main tube, the proximal end (32) of the guide tube, and the flared proximal end (100) of the distal tube to one another by suitable sealing means such as by a solder joint which is a form of heat sealing (line 44 of column 6 to line 14 of column 8). As seen in Figure 2, the guide tube (80) is inserted into the distal tube (82) such that the guide tube proximal end (32) exits and extends from the distal tube flared proximal end (100). Keith discloses the method for manufacturing the catheter structure substantially as claimed. However, Keith is silent on the insertion of expanders into the distal end of the main tube and into the proximal end of the guide tube and on the extraction of the expanders once the sealing has been performed. Zarbatany et al teach inserting expanders into the ends of tubes that will become a lumen for a guide thread or an inflation lumen and removing the expanders after use in the same field of endeavor of using heat-sealing to join the different sections of a catheter structure. The

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expanders maintain the shape of the tubes in the area or zone where the tubes are to be sealed. In Figure 8, Zarbatany et al show the manufacturing assembly of the tubes or catheter structure. Figure 5 shows the tubes or catheter structure assembled for use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Keith by using expanders as taught by Zarbatany et al as Zarbatany et al teach that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure.

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Zarbatany et al as applied to claim 24 above, and further in view of Fitzmaurice et al (U.S. Patent No. 5,823,995). Keith and Zarbatany et al disclose the method for manufacturing the catheter structure substantially as claimed. However, Keith and Zarbatany et al are silent on the specifics of inserting the guide tube into the distal tube before the step of inserting the two expanders. Fitzmaurice et al disclose a method of manufacturing a catheter structure where different components of the catheter structure are assembled before the insertion of expanders or mandrels. Specifically, the wire assembly (14, 50) is placed in the proximal shaft (32) before the mandrel (37) is inserted between the wire assembly and the proximal shaft (lines 36-48 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the guide tube into the distal tube of Keith before inserting the expanders as taught by Fitzmaurice et al as Fitzmaurice et al teach that it is well known to assembly the different components of a catheter structure before inserting expanders into the components.

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9. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Zarbatany et al as applied to claim 24 above, and further in view of Ressemann et al (U.S. Patent No. 6,004,291). Keith and Zarbatany et al disclose the method for manufacturing the catheter structure substantially as claimed. Even though Keith shows the guide tube (80) with an opening (88) on one side of the main tube, Keith and Zarbatany et al are silent on the specifics of trimming the guide tube proximal end so that the guide tube has an opening on one side of the main tube and further are silent on the step of trimming the guide tube proximal end being carried out after the step of extracting the expanders into the distal tube. Ressemann et al disclose a method of manufacturing a catheter structure where a component of the structure, tubing (23), is trimmed to a desired length (lines 7-8 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of manufacturing the catheter structure of Keith with a step of trimming as taught by Ressemann et al as Ressemann et al teach that it is well known to trim components of a catheter structure to the desired length where the length would be dependent on the use of the catheter structure. To trim the guide tube proximal end after the extracting of the expanders would have been obvious to one having ordinary skill in the art at the time the invention was made as it would be difficult and impractical to trim the proximal end of the guide tube while an expander is present in the guide tube.

Response to Arguments

10. Applicant's arguments with respect to claims 23-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767